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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,621

03/10/2004

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EXAMINER

BHATIA, AARTI

ART UNIT

PAPER NUMBER

3763

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DELIVERY MODE

07/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,621	Applicant(s) WULFMAN ET AL.	
	Examiner AARTI BHATIA	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-10, 16-19, 24, 27-29, 32 and 56-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-10, 16-19, 24, 27-29, 32, and 56-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2.14.2007, 8.22.2007, 6.19.2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action based on the 10/798,621 application filed on 3/10/2004. Claims 1-7, 9-10, 16-19, 24, 27-29, 32, and 56-65, as amended on 8/22/2007, are currently pending and have been considered below.

Double Patenting

1. Claims 1-5, 9, 10, 16, 17, 19, 24, 27, and 28 of this application conflict with claims 1-5, 9, 10, 16, 17, 19, 24, 27, and 28 of Application No. 10/798,618.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of US 2002/0007190 to Wulfman et al. or in view of U.S. Patent No. 6,565,588 to Clement et al.

With respect to independent claim 1, Belef teaches an interventional catheter assembly (4) comprising: an operating head (32) coupled to a drive shaft and a drive assembly (22) for rotation and a catheter system mounted for axial translation at a proximal end with a control pod (6) and communicating at a distal end with the operating

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head; and a control pod housing operational components for selectably rotating the operating head.

Belef fails to teach wherein the operating head is adjustable between two different operating diameters and a selection switch that allows an operator to select between two different operating head diameters.

Wulfman and Clement teach catheter assemblies that have adjustable diameters. Further, Wulfman teaches a sliding actuator in communication with the drive system. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the adjustable diameter switch of Wulfman or Clement to facilitate translation and navigation of the device through various lumens (abstract of both Wulfman and Clement).

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of U.S. Patent No. 5,921,956 to Grinberg et al.

With respect to claim 6, Belef teaches an interventional catheter assembly comprising an operating head coupled to a drive shaft and a drive assembly for rotation; a catheter system forming a lumen mounted for axial translation at a proximal end with a control pod and communicating at a distal end with the operating head as described above.

Belef fails to teach a torque selection feature.

Grinberg teaches a catheter assembly with a torque selection controlled by a control unit (114). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the adjustable torque of Grinberg so that the surgeon has control over the catheter assembly (column 7, lines 49-62).

7. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of U.S. Patent No. 5,584,843 to Wulfman et al.

Belef teaches an interventional catheter assembly as described above, but fails to teach a guidewire brake.

Wulfman teaches an interventional catheter assembly with a guidewire brake (column 5, line 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the guidewire brake of Wulfman to control the movement of the guidewire (column 5, lines 14-19).

8. Claims 2, 3, 4, 5, 9, 10, 16, 17, 19, 24, 27, 28, 29, 32, and 58-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,398,755 to Belef et al. in view of U.S. Patent No. 5,921,956 to Grinberg et al., US 2002/0007190 to Wulfman et al., U.S. Patent No. 6,565,588 to Clement et al., and U.S. Patent No. 5,584,843 to Wulfman et al.

Independent claims 1, 6, 18 and 56 are made obvious by the prior art cited above. The features found in dependent claims 2, 3, 4, 5, 9, 10, 16, 17, 19, 24, 27, 28, 29, 32, and 58-65 are also taught or made obvious by the cited references.

Response to Arguments

9. Applicant's arguments filed on 2/14/2007 and 8/22/2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARTI BHATIA whose telephone number is (571)270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763